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ISO 17025 Accreditation Experience at LLNL

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ISO 17025 Accreditation Experience at LLNL



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What is accreditation?

- **Laboratory accreditation is defined as formal recognition of an organization's technical competency to perform specific tests.**
- **LLNL has been accredited by the American Association for Laboratory Accreditation (A2LA).**
- **LLNL has been ISO 17025 accredited since February 2001. The Nuclear Forensic accreditation was granted in July 2006.**



What does the accreditation mean?

In effect, an independent, recognized accreditation body, A2LA, attests that LLNL has demonstrated:

- it is competent to perform specific tests, types of tests, calibrations or types of calibrations listed on its Scope(s) of Accreditation;
- it's management system addresses and conforms to all elements of ISO/IEC 17025, is documented per ISO/IEC 17025, and is fully operational;
- it is operating in accordance with its management system; and;
- it conforms to any additional requirements of A2LA or specific fields or programs necessary to meet particular user needs.



LLNL Accreditation Preparation (Summary)

- Purchase a copy of ISO 17025
- Identify tests for accreditation
- Identify individual in charge of the quality system (*strong top management support*)
- Discuss the relevant components of the accreditation process with applicable individuals.
- Document the policies and procedures in a quality manual and related documentation
- Perform an internal audit or management review to ensure all ISO 17025 requirements are met. Resolve any issues.
- Complete application for accreditation



LLNL Accreditation Process

1. LLNL obtained an official copy of ISO 17025 and confirms this to A2LA by completing and faxing the ISO 17025 Fax Confirmation Form to A2LA.
2. A2LA provided LLNL with an electronic or hard copy version of the ISO/IEC 17025:2005 Assessor Checklist to perform a self-assessment to verify compliance with all requirements. (~60 pages)
3. LLNL completed and returned the full application for accreditation with payment and all required supporting documentation (e.g. organization chart, quality manual, proficiency test plan, deficiency reports (where applicable), completed ISO 17025:2005 checklist, equipment list, etc.)



LLNL Accreditation Process (Con't)

4. A2LA reviewed the application documents and an appropriate assessor(s) is assigned, with laboratory concurrence.
5. The assessor contacted LLNL to discuss the scheduling of the on-site assessment and requested any additional quality documentation that may be needed.
6. The assessment was performed and included: entry briefing; records, sample handling; interviews with scientists; demonstrations of tests/ calibrations; examination of equipment and calibration records; review of quality documentation; written report of assessor's findings; and exit briefing.

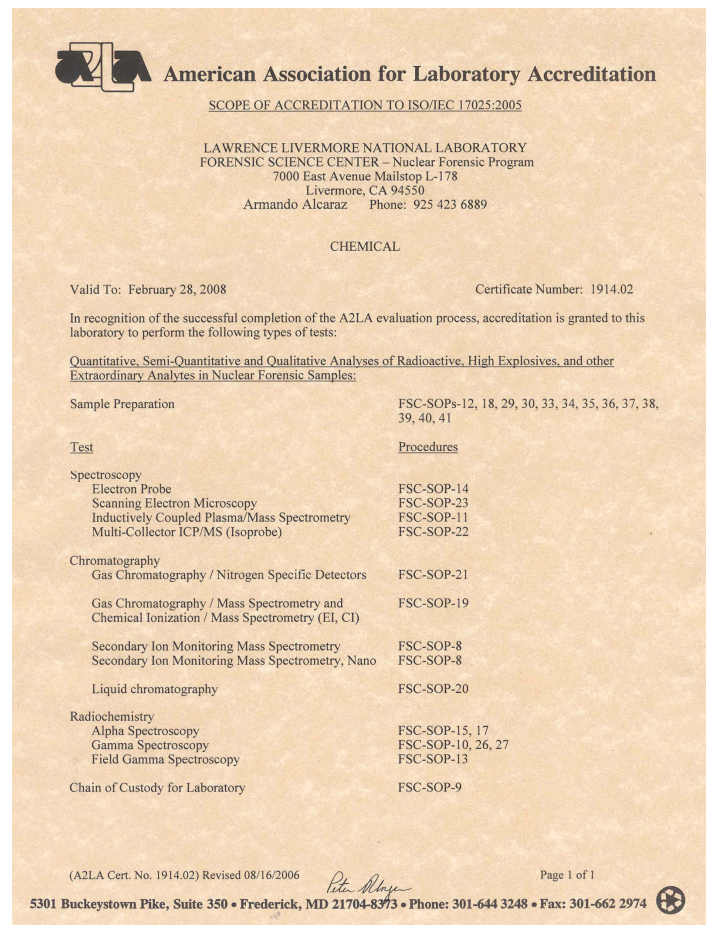


LLNL Accreditation Process (Con't)

7. LLNL responded to any deficiencies with a written corrective action response.
8. The corrective action was reviewed by the A2LA staff and, once complete, was forwarded to the Accreditation Council for a vote.
9. Accreditation was granted when affirmative votes from the Accreditation Council was received, all concerns were resolved, and all fees were paid in full.



LLNL ISO 17025 Accreditation (Cert 1914.02)





LLNL Accreditation Scope for Radioactive, High Explosive and Other Analytes in Nuclear Forensic Samples

Quantitative, Semi-Quantitative and Qualitative Analysis

- **Spectroscopy**

- *Electron Probe*
- *Scanning Electron Microscopy*
- *Inductively Coupled Plasma/Mass Spectrometry*
- *Multi-Collector ICP/MS (Isoprobe)*
- *Secondary Ion Monitoring Mass Spectrometry*
- *Secondary Ion Monitoring Mass Spectrometry, Nano*

- **Chromatography**

- *Gas Chromatography/Nitrogen Specific Detector*
- *Gas Chromatography/Mass Spectrometry and Chemical Ionization/Mass Spectrometry (EI, CI)*
- *Liquid Chromatography*

- **Radiochemistry**

- *Alpha Spectroscopy*
- *Gamma Spectroscopy*
- *Field Gamma Spectroscopy*



Future Accreditation Tests Additions

For High Explosives Detection*

Nuclear Magnetic Resonance

Capillary Electrophoresis

*Liquid Chromatography/ Electrospray Ionization
Mass Spectrometry*

*Liquid Chromatography/ Atmospheric Pressure
Chemical Ionization/ Mass Spectrometry*

* Planned for addition in FY07.



Adding Tests to Existing Scope

To expand tests on an existing scope of accreditation, LLNL will:

- Submit the request to A2LA Headquarters in writing.
- Each request is handled on a case-by-case basis.
- Unless the previous assessor can verify the competence of the laboratory to perform the additional tests, another site visit by A2LA assessor will be required.
- The assessor can recommend a scope addition without a site visit
 - extensive review of supporting documentation required
 - LLNL may be invoiced if the review greater than an hour.
 - If the additional tests require a new technology, another assessment is definitely required.



How much did it cost?

Application Fees

Abbreviations for the fields are:

ACO - Acoustics & Vibration
CMT - Construction Materials
MEC - Mechanical

BIO - Biological
ELE - Electrical
NDT - Nondestructive

CAL - Calibration
ENV - Environmental
THE - Thermal

CHE - Chemical
GEO - Geotechnical

TABLE 1: Fields

Lab Name	ACO	BIO	CAL	CHE	CMT	ELE	ENV	GEO	MEC	NDT	THE
				X							

Add the number of "X's" () and calculate your annual fee using TABLE 2.

Does your laboratory utilize Purchase Orders? Yes _____ No _____

TABLE 2: Fee Calculation

Initial Application Fee
(new lab in the system, first year only)
Annual Fee for first field

Annual Fee for each additional field

Assessor Deposit for first field (estimate) *

Assessor Deposit for each field over 1, add \$2,000 (estimate) *

TOTAL AMOUNT DUE – Please Remit Check Payable to A2LA

As of 1/1/2004	
Fee	Total
\$600	\$600
\$1200	\$1200
\$1000 x	\$0
\$2000	\$2000
\$2000 x	\$0
\$USD	\$3800

(*NOTE: Lab will be billed or refunded the difference between actual cost and this deposit. Accreditation will not be granted until all fees are paid.)

For A2LA Office use Only:

MASTER CODE: ASSESSMENT NO: CERT NO:

IMPORTANT!!

The total costs for the accreditation varies depending on the facility's readiness.

Most of the costs are labor costs.



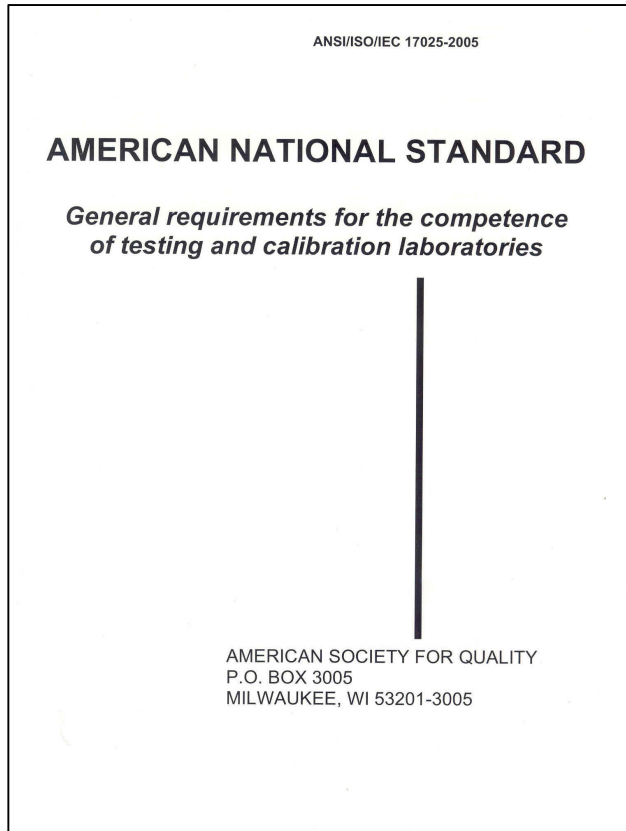
Lessons Learned

- **Buy-In**
- **Cost Estimates**
- **Proficiency Tests**
- **Essential Personnel Identification**



Resources

ISO 17025-2005



Hard Copy Version

*American Society for Quality (ASQ) -
Quality Press Bookstore*

Web site: www.qualitypress.asq.org

Phone: (414) 272 8575 or (800) 248 1946

Global Engineering Documents

Web site: www.global.ihs.com

Phone: (303) 397 7956 or (800) 854 7179

Electronic Version

*American National Standards Institute
(ANSI) Electronic Standards Store (ESS)*

Web site: www.ansi.org

Phone: (212) 642 4900

- **American Association for Laboratory Accreditation**
<http://www.a2la.org/>